

## STATUS OF THE CLAIMS

Claims 1-10 were pending.

Claims 1-9 have been rejected under 35 U.S.C. § 112, first paragraph.

Claim 7 has been rejected under 35 U.S.C. § 112, second paragraph.

Claims 8-9 have been amended.

Claims 3, 7 and 10 have been canceled.

Claims 1, 2, 4-6 and 8-9 are presented for consideration.

## REMARKS

Reconsideration of the above-identified application as amended is requested. Claims 3, 7 have been canceled and claim 10 has been canceled as being drawn to non-elected subject matter. The cancellation of these claims has been done solely to facilitate prosecution and is not an admission as to the propriety of the rejections of claims 3 and 7. The claims have been canceled without prejudice or disclaimer to presenting the subject matter of these claims in one or more divisional or continuing applications.

### Rejection under 35 U.S.C. § 112, first paragraph

Claims 1-9 have been rejected under 35 U.S.C. § 112, first paragraph for alleged lack of enablement. The Examiner states that the specification contains no test results or any experimental data showing the prevention of conditions and diseases associated with IGT or IFG. Applicants respectfully traverse this rejection.

The specification, at page 7, beginning at second full paragraph, carrying over to page 8, identifies a study that confirms that hypoglycemic agents such as insulin enhancers can restore early phase insulin secretion and reduce post-prandial glucose levels in subjects with IGM. Applicants submit that this study clearly provides the evidence necessary for enablement of the claimed invention.

Without an admission as to the propriety of the rejection or to the propriety of the arguments for enablement in the absence of experimental data or test results, Applicants are submitting herewith a poster presented at the World Cardiology Congress (WCC) in Sydney, Australia in March of 2002, as further support that the claims are commensurate in scope with what is enabled by the specification. The poster sets forth evidence that nateglinide has activity commensurate with the disclosed utility. In particular, the poster sets forth substantiating evidence which clearly shows that nateglinide, an insulin secretion enhancer, enhances early insulin secretion and decreases post-prandial glucose concentrations in subjects with IGM. Accordingly, this is evidence of prevention of conditions and diseases associated with IGT because diabetes, as an example, begins with a loss of

insulin secretion. Accordingly, Applicants submit that the claims are commensurate in scope with what is enabled by the specification.

The rejection has also been based on the premise that the specification does not contain any test results or any experimental data showing what types of cancers are being prevented in the human or mammal. The cancellation of claim 3 has rendered this portion of the rejection moot and Applicants have canceled this claim solely to advance prosecution and is not an admission as to the propriety of the rejection.

Applicants respectfully disagree with the statement that the specification does not contain any examples or does not disclose any DPP-IV inhibitors, GLP1 and GLP1 agonist compounds. Representative DPP-IV inhibitors are described in the specification at page 6, first and second full paragraphs. GLP-1 and GLP-1 agonists are also described on page 6. Applicants submit that the ordinarily skilled artisan would immediately know of GLP-1 and GLP-1 agonists which are effective in the claimed invention, for example, see U. S. Pat. No. 5,614,492 issued March 25, 1997. It is established law that the specification omit that which is known to the skilled artisan.

The rejection of the claims under 35 U.S.C. § 112, first paragraph, has been traversed and should be withdrawn.

Rejection under 35 U.S.C. § 112, second paragraph

Claim 7 has been rejected under 35 U.S.C. § 112, second paragraph, as allegedly being vague and indefinite. Without commenting on the propriety of the rejection and solely in an effort to advance prosecution, Applicants have canceled claim 7. This renders the rejection moot. Accordingly, the rejection of claim 7 under 35 U.S.C. § 112, second paragraph, should be withdrawn.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned **“Version with markings to show changes made.”**

In view of the foregoing, Applicant submits the Application is now in condition for allowance and respectfully requests early notice to that effect.

Respectfully submitted,

A handwritten signature in dark ink, appearing to read "Greg Ferraro", is written over a horizontal line.

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**Version with markings to show changes mad**

8. (Once amended) The method of claim ~~7~~1 wherein ~~an insulin secretion enhancer~~ the hypoglycemic agent is selected from the group consisting of a sulfonylurea, repaglinide, nateglinide, a DPP-IV inhibitor, GLP1 and GLP1 agonist, or in in each case, a pharmaceutically acceptable salt thereof.

9. (Once amended) The method of claim 8 wherein the ~~insulin secretion enhancer~~ hypoglycemic agent is nateglinide or a pharmaceutically acceptable salt thereof.